Subpart A—Introduction

§ 627.1 Purpose.

This pamphlet prescribes the technical safety requirements for the use, handling, shipment, storage, and disposal of etiologic agents used in research, development, test, and evaluation (RDTE) for the Biological Defense Program (BDP)

§ 627.2 Background.

The United States Army BDP, on behalf of the Department of Defense, supports RDTE efforts to maintain and develop defensive measures and materiel to meet potential biological warfare threats. The program's objectives are to develop measures for identification, detection, treatment, protection against, and decontamination of these threats. To meet the program objectives, etiologic agents are used to conduct the necessary handling, storage, shipment, and disposal of etiologic agents. This pamphlet describes requirements based on Centers for Disease Control-National Institute of Health (CDC) (NIH) guidelines, Biosafety in Microbiological and Biomedical Laboratories, and establishes guidelines for toxins.

§ 627.3 Scope.

The requirements stated in this pamphlet apply to all elements of the Army to include the ARNG and the USAR and its contractors and subcontractors who use, produce, store, handle, or ship etiologic agents in support of the BDP, regardless of the source of the agent(s).

§ 627.4 References.

Required and related publications are listed in appendix A of this part.

§ 627.5 Abbreviations and terms.

Abbreviations and special terms used in this part are explained in appendix F of this part.

Subpart B—Administration

§ 627.6 Safety administration.

Each BDP institution must have a safety program that complies with AR 385–10, AR 385–69, and this pamphlet. In addition, the safety program must be designed to ensure compliance with—

(a) Occupational Safety and Health Administration (OSHA) requirements for health and safety.

(b) Environmental Protection Agency (EPA) regulations designed to implement the Resource Conservation and Recovery Act (RCRA) and the National Environmental Policy Act (NEPA).

(c) Nuclear Regulatory Commission (NRC) requirements for safe handling of radioactive isotopes (when applicable).

(d) NIH Guidelines for Research Involving Recombinant Deoxyribonucleic Acid (DNA) Molecules.

(e) Relevant national, State, and local regulations.

(f) Any requirements of applicable accrediting bodies.

§ 627.7 Goal of a laboratory safety program.

The goals of the laboratory safety program are to protect those working in the laboratory, others who may potentially be exposed to hazards in the laboratory, and the environment. In addition, a laboratory safety program should ensure that hazardous materials will be handled and disposed of in such a way that people, other living organisms, and the environment are protected from harm. Safety awareness must be a part of everyone's habits, and can only be achieved if all senior and responsible staff have a sincere, visible, and continuing interest in preventing injuries and occupational illnesses. Laboratory personnel, for their part, must carry out their work in a way that protects themselves and their fellow workers.

(a) *Laboratory safety*. The safety program will be carried out as stated in AR 385–69. Additionally, the program will contain the following elements—

(1) The commander or institute director, along with all personnel, must have a continuing, observable, and known commitment to the safety program.

(2) An effective institutional safety program requires a safety officer appropriately trained in relevant safety technology. This individual, besides supplying advice and recommendations, will ensure that records are kept

showing that the institution's physical facilities and safety rules are internally consistent and compatible with potential risks, as well as in compliance with all applicable laws, regulations, and guidelines.

(3) The commander ensures safety in every department or other equivalent administrative unit of the institution. Ensuring safe operations is an integral function of each level of management through the first line supervisor. The safety office staff must work closely with administrators and investigators to develop and implement written policies and practices that promote safe laboratory work. Collectively, this group routinely must monitor current operations and practices, see that appropriate audits are maintained, and continue to seek ways to improve the safety program.

(4) Safety is a critical job element for each member of the scientific and technical staff. Each individual working in the laboratory must perform his or her job in a manner consistent with safety policy and training.

(5) If laboratory goals dictate operations or substances not suited to the existing facilities or equipment, the laboratory supervisor will, assisted by the safety officer, advise and assist the laboratory worker in developing or obtaining adequate facilities or equipment and designing appropriate work procedures.

(6) The supervisor will authorize each specific operation, delineate appropriate safety procedures, and instruct those who carry out the operation.

(7) Potential hazards will be identified before work with etiologic agents begins, and actions necessary to avoid accidents and illnesses will be implemented. This practice, called a job safety analysis, consists of breaking a job down into its logical steps, analyzing each for its hazard potential, and deciding the safe procedures to use. The process will be designed by a project director with input from employees, and each step with potential for exposure or other incidents must be described in writing in a standing operating procedure (SOP). All such SOPs will be approved by, at a minimum, the commander or institute director and the safety officer.

(8) The job safety analysis will include a consideration of health hazards identified in AR 40–10 and of maximum credible events as described in paragraph 2–8, AR 385–69.

(b) *Safety plans.* Clearly defined, published safety rules and monitoring procedures for compliance must be established. These rules will be readily available, in writing, for all involved in laboratory operations. This goal may be accomplished by preparing or modifying a facility safety plan, laboratory safety manual, occupational safety and health program or equivalent. This plan will—

(1) Be coordinated with institutional and Federal, State, and local emergency services.

(2) Be practiced with the emergency groups whose services are part of that plan prior to any need for their services, so that they can become familiar with any potential problem areas that may be encountered when they are called upon for assistance.

(3) Describe the method of rapid communication (for telephone, alarms, and so forth) that will be used during an emergency.

(4) Describe the institution's etiologic agent labeling system.

(5) Describe the institution's requirements for testing engineering controls (for example, biological safety cabinets and high efficiency particulate air (HEPA) filters) and essential safety equipment (for example, autoclaves) that are used to conduct RDTE funded by the BDP.

(6) Appoint and train personnel responsible for handling an emergency.

(7) Require that emergency telephone numbers be posted, so that emergency service personnel know whom to contact at all times of the day or night.

(8) Describe the institution's rules that have been established and are practiced to limit access to the facilities where etiologic agents under the sponsorship of the BDP are handled. The rules will include the following requirements:

(i) Access to biosafety level (BL)–1 and BL–1 large-scale (LS) laboratories is limited or restricted at the discretion of the commander or institute director when experiments are in progress.

(ii) Access to areas classified as BL–2, BL–2 LS, or where work with toxins is conducted, is limited by the commander or institute director when work with etiologic agents is in progress. Individuals who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory. Only persons who have been advised of the potential hazard and meet any specific entry requirements (for example, immunization) may enter the individual laboratory or animal rooms. The commander or institute director must assess each circumstance and determine who may enter or work in the laboratory.

(iii) Access to areas classified as BL–3 or BL–3 LS is limited as stated in §627.7(b)(8)(ii), and is restricted to those persons whose presence in the facility or individual laboratory rooms is required for program or support purposes. Individuals under 18 years of age may not enter the controlled area.

(iv) Access to BL–4 facilities is limited as stated in §627.7(b)(8) (ii) and (iii). This is done with secure, locked doors with access controlled by the commander or institute director, safety officer, or other person responsible for the physical security of the facility. Before entry, all persons will be advised as to the appropriate safeguards for ensuring their safety. Authorized persons must comply with these instructions and all other applicable entry and exit procedures. A logbook will be maintained for all personnel to indicate the date and time of each entry and exit. A card-key activated computer record (or other electronic entry device) may be used if it indicates the date and time of both entry and exit.

(9) Describe the system that is developed and is operational for the reporting of accidents and exposures, employee absenteeism, and for the medical surveillance of potential laboratory-associated illnesses.

(c) *Safety meetings and safety committees.* In effective safety programs, everyone associated with the laboratory becomes involved. This is done by ensuring maximum participation in planning and by conducting group safety meetings.

(1) A staff safety committee, consisting of the commander or institute director or his or her designated representative, research supervisors, managers, medical personnel, employees, and the safety officer, will be established. This group leads the safety effort, reviews mishaps, and recommends changes in policies, safety program, or equipment as needed to improve safety.

(2) Safety committees will meet at least quarterly and minutes will be prepared and maintained for at least 3 years.

(3) When work with recombinant DNA molecules is undertaken, an institutional biosafety committee (IBC) for review of such work will be established and will function as stated in the NIH Guidelines for Research Involving Recombinant DNA Molecules (see appendix A to this part).

(d) *SOPs.* Besides the documented safety program that will be in effect, each institution will require that an SOP be established for each unique biological defense RDTE operation. The SOPs will meet the criteria stated in AR 385–69 and be reviewed and updated annually. A copy of the SOP will be maintained in the work area. In addition, SOPs will address the following issues—

(1) The unique hazards introduced by the activity in the work area.

(2) The methods of controlling these hazards.

(3) Any unique procedures and requirements needed that are not described as universally required in the safety plan (for example, signs, waste disposal, immunizations, emergency procedures, and personnel monitoring).

(4) Specialized orientation or training of personnel beyond that required in the safety plan.

(5) Ways of ensuring that the unique procedures are followed.

(6) Emergency procedures.

(e) *Safety communications.* Safety communications alert people to newly recognized hazards, remind them of basic biological safety principles, and instill positive attitudes toward safety. Training requirements are also found in §627.10(b). A system of communication will be established to—

(1) Implement a biological safety training program for all personnel

working with hazardous biological or chemical materials.

(2) Publish information addressing useful biological safety advice and accounts of laboratory accidents, along with the lessons to be learned from them.

(3) Make reference books and regulations concerning laboratory hazards, occupational health, and proper laboratory practices readily available.

(4) Assure that material safety data sheets (MSDS) for hazardous chemicals used in the laboratory are readily available to all employees.

(f) *Safety audits.* One of the essential elements of a good safety program is the conduct of periodic audits of the safety performance in a laboratory. Observing individual safety practices and checking the operability of safety equipment and compliance with safety rules must be part of the audit.

(1) An individual and an alternate will be appointed for each laboratory or room where BDP work is conducted. On a daily basis he or she will monitor the conduct of personnel within their room(s) and maintenance of the room to see that they comply with the safety program and SOPs.

(2) Supervisors will ensure that their projects comply with applicable safety requirements and will audit their areas at least weekly to ensure compliance.

(3) The safety officer or his or her qualified designee will inspect the institution's BL–1, BL–2, and toxin laboratories quarterly. BL–3 and BL–4 laboratories and those in which dry forms of highly potent toxins are handled will be inspected monthly by safety and health professionals. These inspections will be announced and include coverage of general safety practices as well as features specific to a particular biosafety level.

(i) Reports of deficiencies or procedures that create a potentially life-threatening situation will be made directly to supervisory personnel and the commander or institute director and actions will be taken immediately to correct the situation. The operation will not continue until every deficiency is corrected.

(ii) Reports of deficiencies for other than life-threatening situations will be made as soon as possible to the appropriate supervisor, with copies furnished to the commander or institute director. If a problem is widespread, all affected personnel will be notified.

(4) Supervisory personnel notified of safety deficiencies by the safety officer will ensure that the people directly concerned are contacted and that the deficiencies are remedied before operations are resumed.

(5) Malfunctioning equipment must be reported to the appropriate individuals, labeled to indicate that it should not be used, and repaired promptly.

(6) As a minimum, the audits conducted by the safety officer or his or her qualified designee will cover the items listed in appendix C to this part.

(g) *Documentation.* Records, documenting the following items, will be maintained for 3 years:

(1) Safety audits and the corrective measures.

(2) Risk assessments for proposed new laboratory procedures.

(3) Annual reviews of established SOPs.

(4) Training.

(5) Engineering controls and protective equipment certifications and tests.

(6) Safety committee meeting minutes and recommendations.

(7) Any outside auditor comments and responses.

§ 627.8 Occupational health.

An occupational health program will be implemented per AR 40–5, chapter 5, for all employees whose employment requires that they conduct duties in a BDP etiologic agent area. Essential elements of the program will include—

(a) *Medical surveillance examinations.* Medical examinations by a licensed medical doctor will be given prior to employment, at least every 3 years thereafter, and upon termination of duties requiring access to laboratories where etiologic agents are used. When full medical examinations are not given annually, health professionals will perform annual health screening. Safety and health professionals will ensure that medical examiners are made aware of all hazardous substances each employee works with at the time of the medical examination. The physician's findings will include assessment of whether an employee has any health